

ELAP Preliminary Draft Regulations Workshop



Agenda

1. Opening Statements
2. Safety and Introductions
3. CWEA: Sign In Sheet and Training Hours
4. Timeline
5. How to Submit Comments
6. Preliminary Draft Regulations Overview
7. Open to Audience for Comments

Opening Statements

- ELAP is an essential program to the Water Board and various environmental/public health regulatory agencies
- Regulations development is a Water Board priority project
- This effort is one of several transformative initiatives ELAP has implemented as recommended by an Expert Review Panel
- Thank you for your attendance and participation

Opening Statements

- The purpose of this workshop is to:
 - **Clarify** the Preliminary Draft Regulations text
 - **Encourage** comments
 - **Answer** questions

Safety

- In the event of an emergency we will follow site specific evacuation procedures



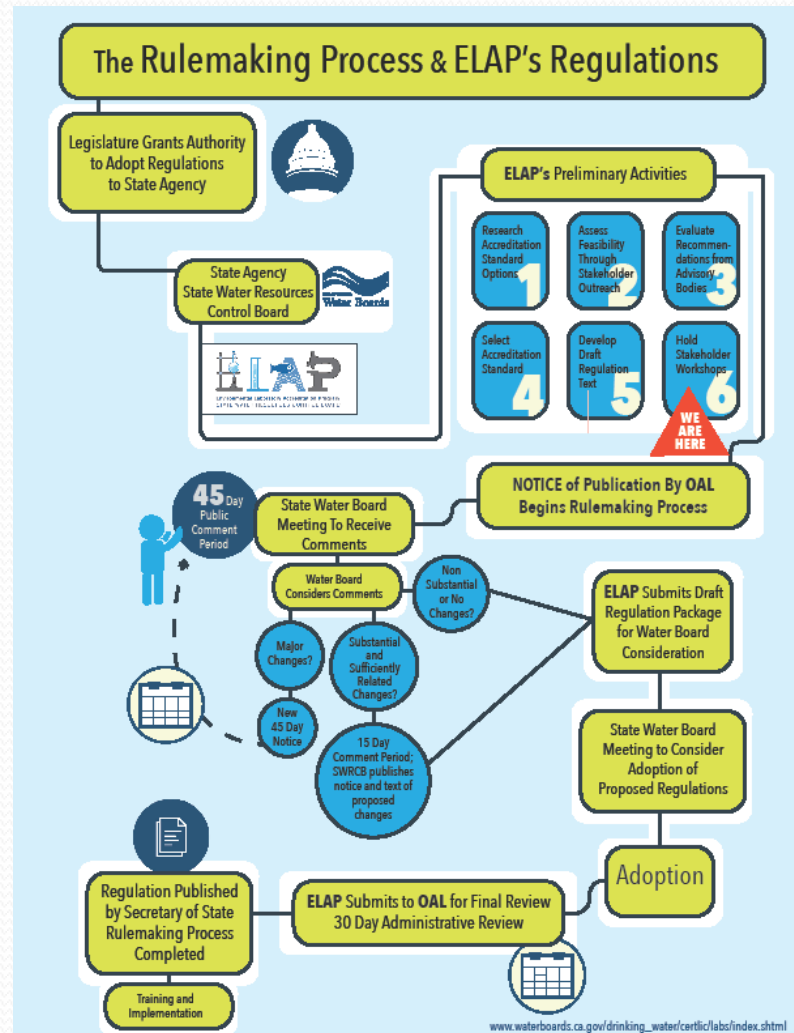
Introductions

- Christine Sotelo
 - *ELAP Chief*
- Maryam Khosravifard
 - *Senior Environmental Scientist (Supervisor)*
- Jacob Oaxaca
 - *Environmental Scientist*
- Katlin Bloom
 - *Environmental Scientist*
- Cheyene Keniston
 - *Environmental Scientist*

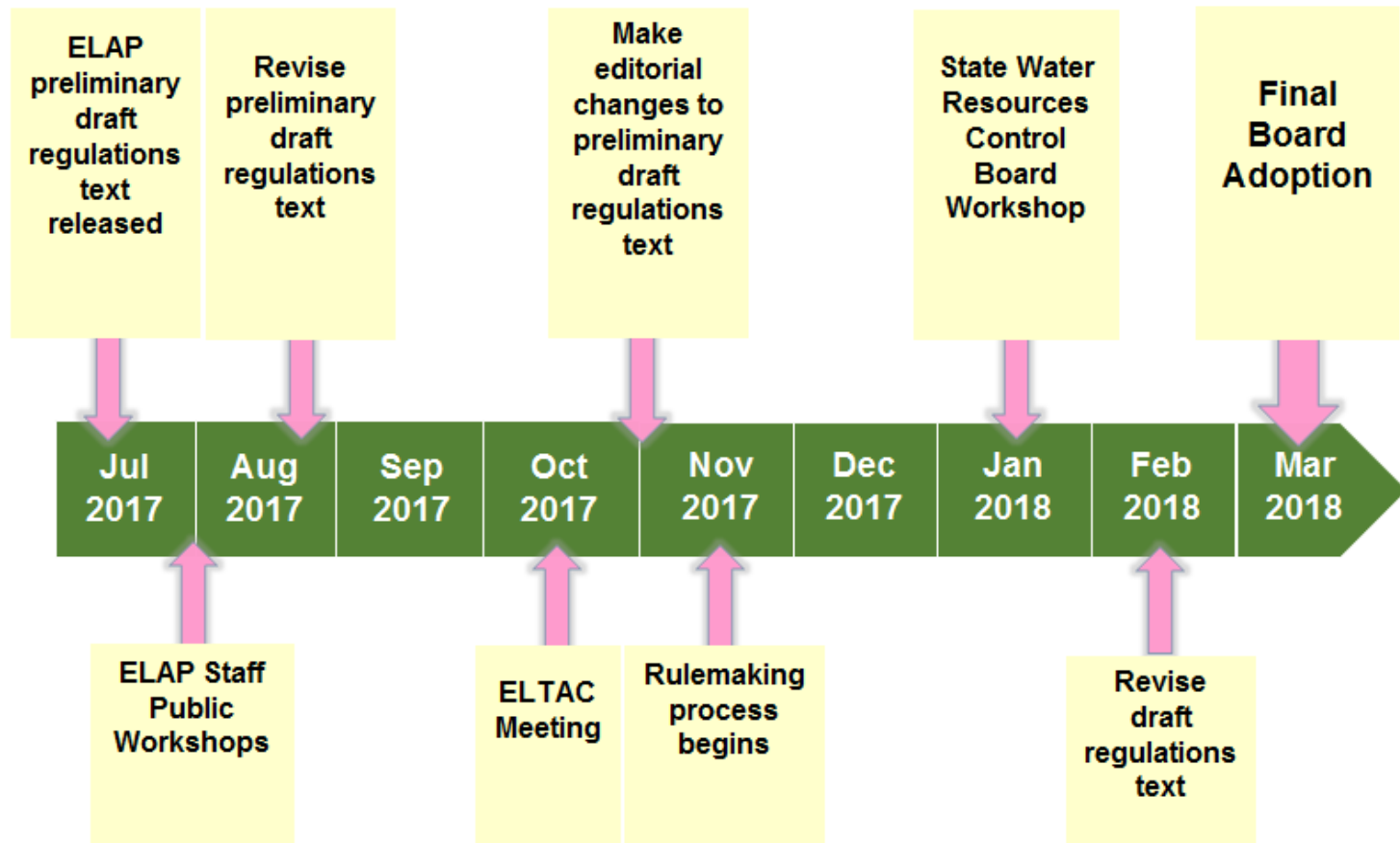
CWEA/CA-NV AWWA Training Credit

- Sign in sheet
- Training hours

The Rulemaking Process



Projected Timeline



Public Comments

- **Grab a handout!**
- Comments are encouraged
- Submit written comments on the Preliminary Draft Regulations text by **September 7, 2017; 5:00 p.m.**

How to Submit a Comment

1. By email:

Email: elapca_comments@waterboards.ca.gov

Use subject line: ELAP Preliminary Draft
Regulations Comments

2. By mail:

Environmental Laboratory Accreditation Program
(ELAP)

Preliminary Draft Regulations Comments

P.O. Box 100, Sacramento, CA 95814

How to Form Effective Comments

- **Identify the specific section** of the text that you are commenting on.
- **Be concise** and focus directly on the ELAP Preliminary Draft Regulations text.

Preliminary Draft Regulations Overview

- Article 1 – Definitions
- Article 2 – Accreditation Requirements
- Article 3 – Types of Accreditation
- Article 4 – Types of Laboratories
- Article 5 – Laboratory Personnel and Equipment
- Article 6 – Notification/Sale of Ownership
- Article 7 – Denial, Suspension, or Revocation

Article 1 – Definitions

- The relevant definitions listed in the 2016 TNI Standard, Volume 1 apply throughout this regulation except as otherwise defined in this section

Article 2 – Accreditation Requirements

- **General Accreditation Criteria**

- Adds compliance with 2016 TNI Standard, Volume 1
- Changes requirement for on-site assessment from every two years to when required

- **Application**

- Updates application
- Reduces the number of days a laboratory has to correct an **incomplete renewal application** from 90 days to 30 days
- All applications will be due by same date annually, rather than a rolling basis

Article 2 – Accreditation Requirements

- **Quality Systems (Laboratory Standards)**

- Incorporates 2016 TNI Standard, Volume 1 by reference
 - With the exception of technical manager qualifications
- Three year delayed compliance with TNI requirements upon adoption of regulations
 - Early TNI adopters will be given priority status and reduced accreditation process time
 - Delayed TNI adopters will be required to submit quarterly reports documenting quality assurance

- **Field(s) of Accreditation**

- Field(s) of Accreditation tables repealed from regulations and moved to ELAP's website, which will be updated to address ongoing needs of agency partners

Article 2 – Accreditation Requirements

- **Proficiency Testing**

- PT requirements consistent with 2016 TNI Standard, Volume 1 (with the exception of PT frequency)
- Requires acceptable PT scores prior to application for accreditation
- Modifies PT requirements for toxicity bioassay
- Accreditation suspended for failing to achieve acceptable PT scores on two consecutive PT Studies during annual and renewal cycles
 - Includes requirements for reinstatement after suspension
- Adds requirement for alternative demonstration of capability when there is no PT study available for California specific analytes

Article 2 – Accreditation Requirements

- **On-Site Assessment**

- Adds detail to Corrective Action report requirements, including timelines for:
 - Laboratory submittal of Corrective Action Report (30 days)
 - ELAP response to Corrective Action Report (30 days)
 - Laboratory submittal of revised Corrective Action Report (30 days)
- If a revised corrective action report still does not satisfactorily address findings, accreditation shall be denied, suspended or revoked for any Field(s) of Accreditation and/or Unit(s) of Accreditation affected by failure to take corrective action.

Article 3 – Types of Accreditation

- **Renewal Accreditation**

- Introduces monetary fines for late submittal of renewal application
 - Late applications may result in a gap in accreditation

- **Amendment Accreditation**

- Specifies types of amendments
 - Change of laboratory name
 - Change of laboratory location
 - Adding an auxiliary laboratory
 - Adding or modifying scope of accreditation
- Addresses variances in requirements for each type of amendment
 - Timelines for notification
 - Required documentation to be submitted
 - Frequency of on-site assessments

Article 3 – Types of Accreditation

- **Interim Accreditation**
 - Clarifies ELAP's use of interim accreditation
- **Reciprocity Accreditation**
 - ELAP accreditation will no longer remain valid if a laboratory's primary accreditation is expired, suspended or revoked

Article 4 – Types of Laboratories

- Defines criteria for each type of laboratory
 - Stationary, Auxiliary, and Mobile
- Adds additional criteria to existing definition of auxiliary laboratory
 - Must be included in primary laboratory's quality manual
- Allows a laboratory to combine a stationary and mobile laboratory under a single accreditation (under certain conditions)

Article 5 – Laboratory Personnel and Equipment

- **Laboratory Personnel**

- Renames Laboratory Director as Technical Manager
 - Retains existing education and experience qualifications
- Removes allowance for a person(s) with lesser qualifications to temporarily serve in the Technical Manager's absence
- Removes educational and experience requirements for Principal Analyst and allows laboratory management to define

Laboratory and Equipment

- Incorporates 2016 TNI Standard, Volume 1

Article 6 – Notification/Sale of Ownership

- **Client Notification**

- Added 48 hr notification requirements for perchlorate and chlorine dioxide
- Allows subcontractor laboratories to perform notification
- Added requirement for submittal of bacterial monitoring report when reporting bacterial quality results
- Added requirements for electronic reporting of:
 - Domestic Water Quality and Monitoring
 - Disinfectant Residuals, Disinfection Byproducts, and Disinfectant Byproduct Precursors
 - Lead and Copper.

Article 6 – Notification/Sale of Ownership

- **ELAP Notification**

- Change of technical manager and/or quality manager
- Change of sophisticated instrumentation

- **Reporting**

- Standardizes reporting requirements in accordance with 2016 TNI Standard, Volume 1, Module 2, Sections 4.5, 4.13, and 5.10

- **Sale or Transfer of Ownership**

- Extends notification time frame from 15 to 30 days
- Requires record retention for the previous 5 years to continue operation under original certificate
- Removes mandatory site visit and PTs for use of certificate to its expiration date

Article 7 –Denial, Suspension, or Revocation

- **Denying, Suspending, or Revoking Accreditation**
 - Establishes criteria for denial, suspension, or revocation of accreditation
 - Establishes measures to allow data users to assess data quality from revoked laboratories:
 - Remove reference to ELAP accreditation
 - Return certificate
 - Cease all testing for regulatory purposes
 - Notify all regulatory clients
 - Provide a list of regulatory clients affected
 - Discontinue subcontracting agreements with accredited laboratories after 7 days



Comments on Article 1

Definitions



Comments on Article 2

Accreditation Requirements



Comments on Article 3

Types of Accreditation



Comments on Article 4

Types of Laboratories



Comments on Article 5

Laboratory Personnel and Equipment



Comments on Article 6

Notification/Sale of Ownership



Comments on Article 7

**Denial,
Suspension, or
Revocation**

Next Steps

- Compile comments for possible revision
- Prepare Draft Regulations package



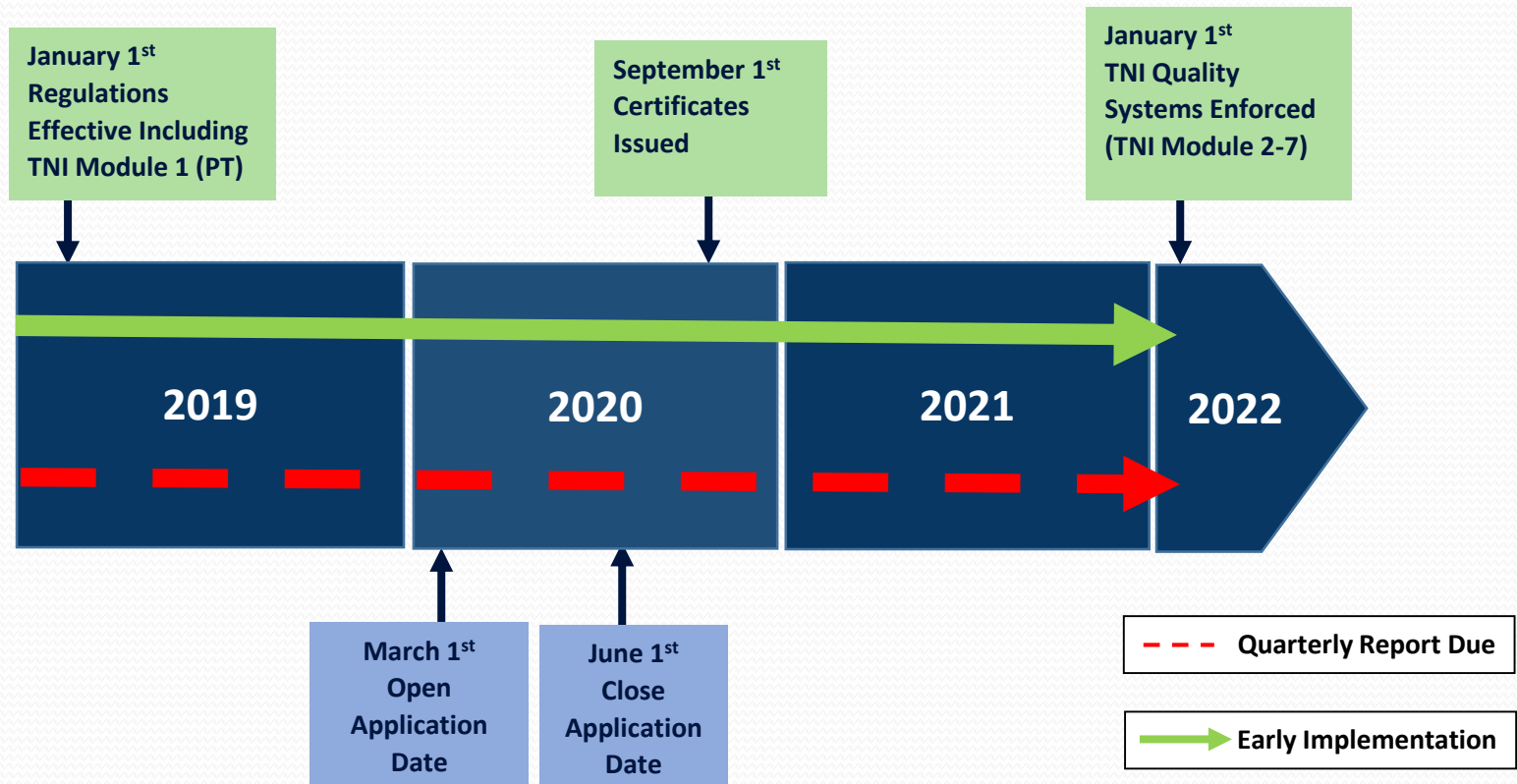
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- Comments: elapca_comments@waterboards.ca.gov

Additional Workshops

- Six locations throughout California:
 - Fresno – July 25, 2017
 - Sacramento – July 26, 2017
 - Redding – July 28, 2017
 - Los Angeles – August 1, 2017
 - San Diego – August 2, 2017
 - San Francisco – August 3, 2017
- The **last day** to submit comments on the Preliminary Draft Regulations text is **September 7, 2017 by 5:00 p.m.**
 - elapca_comments@waterboards.ca.gov

Pathways to Compliance



Laboratory Director = Technical Manager

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graph TD; A[Laboratory Director = Technical Manager] --> B[Analyst = Technical Personnel]; A --> C[Principal Analyst = Technical Personnel]; A --> D[Quality Manager]
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Analyst =
Technical
Personnel

Principal Analyst =
Technical
Personnel

Quality Manager